Initial Review    Continuing Review    Response to Deferral

Change in Protocol/FYI, or    Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PI materials dated: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB REVIEWER'S CHECKLIST – FULL REVIEW

Review for IRB Meeting Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **Reviewer(s):** |  |  | **IRB #:** |  |
|  |  |  | **Date:** |  |
| Investigator |  |  | **Due date:** |  |

Enclosed is a **HUMAN RESEARCH APPLICATION and PROTOCOL** for IRB Review. The investigator should have addressed each of the categories listed below. Please check if the information is adequate and meets the guidelines for IRB approval. Provide your comments below or on additional pages using the same numbers as used for each category.

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|  | **YES** | **NO** | **NA** |
| **Initial review materials received** |  |  |  |
| 1. IRB Cover Sheet, *required* (summary email is sufficient) |  |  |  |
| 1. IRB Full Review Application, *required*  * The first page of the IRB application must be signed by all investigators |  |  |  |
| 1. Proposed informed consent document, required |  |  |  |
| 1. Survey instrument(s) and/or experimental procedure as applicable, required |  |  |  |
| 1. Recruitment materials for subjects, required |  |  |  |
| 1. Human Subjects training completion certificates for ALL investigators, required |  |  |  |
| 1. Letter(s) of Approval from cooperating entities (Letter from district or principal if conducting research in schools), if applicable |  |  |  |
| 1. Relevant grant applications, if applicable |  |  |  |
| 1. Investigators brochure (a comprehensive document summarizing the body of information about an investigational product), if one exists |  |  |  |
| 1. If study is supported by the Department of Health & Human Services, a copy of the HHS approved sample, informed consent form, and HHS protocol, if they exist |  |  |  |
| **If any of the applicable review materials have not been received, please notify the IRB Chair in writing. The review should only continue once all applicable review materials have been received.** |  |  |  |

**YES NO NA**

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| 1. **ABSTRACT** |  |  |  |
| 1. Abstract describes study procedures sufficiently |  |  |  |
| 1. Abstract describes duration of project (including time subjects will take part) |  |  |  |
| 1. Abstract describes benefits/risks of research to subjects and society |  |  |  |
| 1. Abstract describes how confidentiality/anonymity of subjects will be maintained |  |  |  |
| 1. **DESIGN** |  |  |  |
| 1. Factors/conditions/variables/groups for study are described sufficiently |  |  |  |
| 1. Number of subjects assigned to each condition is provided |  |  |  |
| 1. Plans for data analysis are described sufficiently |  |  |  |
| 1. **RESEARCH PARTICIPANTS** |  |  |  |
| 1. Approximate number of participants is provided and targeted groups are identified |  |  |  |
| 1. Any vulnerable populations are identified and justified |  |  |  |
| 1. Inclusion/exclusion criteria are provided and are appropriate |  |  |  |
| 1. Recruitment procedures are clearly described |  |  |  |
| 1. Authorization letters are provided from any sites other than CSU |  |  |  |
| 1. Working relationship between researcher and subjects (if present) is appropriate |  |  |  |
| 1. Incentives to participants are appropriate |  |  |  |
| 1. **PROCEDURES** |  |  |  |
| 1. Activities required from research participants are described |  |  |  |
| 1. Researcher’s interaction with subjects is appropriate |  |  |  |
| 1. Duration/time commitment of participants is appropriate |  |  |  |
| 1. **MATERIALS** |  |  |  |
| 1. All written materials used in procedure are provided with application (including interview script(s) if appropriate) |  |  |  |
| 1. **RISK** |  |  |  |
| 1. Current risks to research participants are described sufficiently and are appropriate to study |  |  |  |
| 1. Future risks to research participants are described sufficiently and are appropriate to study |  |  |  |
| 1. Procedures for maintaining anonymity/confidentiality of data are appropriate |  |  |  |
| 1. **BENEFIT** |  |  |  |
| 1. Potential benefits to participants are identified |  |  |  |
| 1. Potential benefits to society are identified |  |  |  |
| 1. **INFORMED CONSENT** |  |  |  |
| 1. Process for obtaining informed consent is appropriate |  |  |  |
| 1. If deception will be used in the study, necessity is justified, and debriefing procedures are described |  |  |  |
| 1. Consent documents are included with application and include all required components |  |  |  |
| 1. If personal health information is collected, its collection and use is described adequately |  |  |  |
| 1. **CONSENT FOR VULNERABLE POPULATIONS** |  |  |  |
| 1. Procedures to obtain consent/assent from vulnerable populations are described an are appropriate |  |  |  |
| 1. Process for obtaining informed consent from parent(s)/guardian(s) is appropriate |  |  |  |
| 1. **OFF-CAMPUS STUDY SITES** |  |  |  |
| 1. If project will involve work off campus, all sites are listed |  |  |  |
| 1. Authorization letters are provided from all off-campus sites |  |  |  |

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| **CONSENT DOCUMENT(s)** | **YES** | **NO** | **NA** |
| 1. **Purpose** of the research – Why is this study being done? |  |  |  |
| 2. **Participation** or study procedures- What am I being asked to do? |  |  |  |
| 3. **Duration**- How long will I be in the study? |  |  |  |
| 4. **Risks**- What are the Risks |  |  |  |
| 5. **Benefits**- Are there benefits to being in this study? |  |  |  |
| 6. **Alternatives**- What other options are there? |  |  |  |
| 7. **Confidentiality** / privacy- Will my information be kept private? |  |  |  |
| 8. **Costs** and payments- What are the costs and payments? |  |  |  |
| 9. **Research related** **injury**- What happens if I am injured …? |  |  |  |
| 10. **Contacts**- Who can I call if I have questions? |  |  |  |
| 11. **Voluntary participation** / right to withdraw- What are my rights…? |  |  |  |
| 12. **Statement of consent**- How can I be sure I understand? |  |  |  |
| Signature Lines I be sure I understand?ons??study? class reunion right now, but I am more than happy to help in anyway.ilable dates. |  |  |  |
| Is the consent document clearly written in *lay language*? |  |  |  |
| **HIPAA AUTHORIZATION** (if study involves PHI): in sect. 7 of consent or separate doc. | | | |
| * Sources and types of PHI are identified – (Should match section F4b of IRB application) |  |  |  |
| * Sample PHI statements selected |  |  |  |
| * Inclusion of all possible recipients of PHI disclosure |  |  |  |
| * Inclusion of sponsor’s name who may use and disclose PHI containing records- (Should match section F5c of IRB application) |  |  |  |
| * Inclusion of the statement regarding expiration |  |  |  |
| * Inclusion of PI’s name and contact information for revocation of authorization |  |  |  |

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|  | **APPROVAL** | |  |
| **If Standard Consent Document is Not Provided** | **YES** | **NO** | **N/A** |
| Waiver of written consent justified on the Waiver of Consent form? ([45 CFR 46.117](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117)) ([FDA](http://a257.g.akamaitech.net/7/257/2422/10apr20061500/edocket.access.gpo.gov/cfr_2006/aprqtr/21cfr56.109.htm)) |  |  |  |
| Waiver of consent altogether justified on the Waiver of Consent Form?  [45 CFR 46.116](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116) / [NIH](http://fr.cos.com/cgi-bin/retrieve?db=fr_1996&ac2=19961002a95) or [FDA](http://a257.g.akamaitech.net/7/257/2422/10apr20061500/edocket.access.gpo.gov/cfr_2006/aprqtr/21cfr56.109.htm) emerg use |  |  |  |
| Alteration or Short Form consent acceptable? ([45CFR46.116/7](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116)) ([FDA](http://a257.g.akamaitech.net/7/257/2422/10apr20061500/edocket.access.gpo.gov/cfr_2006/aprqtr/21cfr50.27.htm)) |  |  |  |

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| **SPECIAL CONSIDERATIONS** | ***N/A*** | ***or other determinations*** | | | |
| [Medical device studies](http://www.fda.gov/oc/ohrt/irbs/devrisk.pdf): |  | Non-Significant risk | | Significant Risk | |
| University Indemnified study - level of risk: |  | Low | Medium | | High |
| Subpart B:  Pregnant women, neonates, and fetuses |  | Meets criteria under [45 CFR 46.204/205/206](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartb) and  Necessity of consent of father has been addressed | | | |
| Subpart C: Prisoners as subjects |  | Meets criteria under [45 CFR 46.305](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.305) | | | |
| Subpart D: Children  NOTE: For research under §46.406 and §46.407, permission is to be obtained from both parents per  [45 CFR 46.408](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.408). |  | ([45 CFR 46.404](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.404)) No greater than minimal risk | | | |
|  |  | ([45 CFR 46.405](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.405)) More than minimal risk; Prospect of direct benefit to individual subjects | | | |
|  |  | ([45 CFR 46.406](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.406)) Minor increase over minimal risk; No prospect of direct benefit to individual subjects but likely to yield generalizable knowledge about subject’s disorder/condition. | | | |
|  |  | ([45 CFR 46.407](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.407)) Not otherwise approvable but opportunity to understand, prevent or alleviate serious problem affecting children | | | |
| Will child reach legal age during study? |  | Adequately addressed (see [OHRP children FAQ #4](http://www.hhs.gov/ohrp/policy/index.html#children)) | | | |

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| **Level of risk:** |  | No more than minimal risk |  | Minor increase over  minimal risk |  | More than minor increase  over minimal risk |
| **Length of approval due to level of risk:** | 1 yr: | | If less than 1 year, indicate period: | | | |

**I have reviewed the enclosed Protocol and recommend:**

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| **Full Approval** |  | **\*Contingent Approval** |  | **Deferral** |  | **Disapproval** |  |

***\*Contingencies must stipulate specific revisions requiring simple concurrence by the investigator. Substantive clarifications/modifications to the protocol or consent must have subsequent review by the convened Board.***

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| Signature of Reviewer |  | Date |
| For studies that meet expedited category(ies) of research, indicate category #s | | |  |